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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,959	10/30/2003	Craig C. Hodges	00020.08CON	8482

7590 01/27/2005

IP Department
Alexza Molecular Delivery Corporation
1001 East Meadow Circle
Palo Alto, CA 94303

EXAMINER

HAGHIGHATIAN, MINA

ART UNIT PAPER NUMBER

1616

DATE MAILED: 01/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/696,959	Applicant(s) HODGES ET AL.	
	Examiner Mina Haghighatian	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>09/24/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the amendments and remarks filed 12/17/04.

Accordingly no claims are cancelled and no new claims added. Claims 1-17 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 17 are vague for reciting the term "the stable number concentration of particles". It is not clear what number concentration is defining.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howell et al (5,743,251).

Howell et al teaches aerosols formed by supplying a material in liquid form to a tube and heating the tube such that the material volatilizes and expands out of an open

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end of the tube. The volatilized material combines with ambient air such that volatilized material condenses to form the aerosol (see abstract). The aerosols have an average mass median particle diameter of less than 2 microns to facilitate deep lung penetration. The drug is delivered at a rate of above 1 mg/sec (see col. 2, lines 1-9). The device contains a thin platinum layer and an aluminum tube (see col. 3, lines 60-66). The thin film heater layer is deposited on the ceramic tube. The heater layer is preferably a thin platinum film having a thickness of less than 2 microns (col. 4, lines 12-20). The fluid is said to be fed at a rate of 1.5 mg/sec (col. 12, lines 33-36).

Although Howell et al does not state the method steps for the preparation of a condensation aerosol as recited in the instant claims, the modifications would have been obvious to one of ordinary skill in the art. Howell provides sufficient disclosure for one of ordinary skill in the art to make and use the invention as claimed. The formation of particles with a mass median diameter of less than 2 micron reads on the limitation of 0.1 micron.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent Nos. 6776978, 6716417, 6797259, 6740309, 6743415, 6737042, 6814955, 6805584, 6716415, 6803031, 6759029, 6737043, 6740308, 6740307, 6716416, 6783753, 6780400, 6780399, 6805853 and 6814954. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are anticipated by the reference claims. Claims of the instant application are generic to all that is recited in claims of the said U.S. Patents. That is, claims of the said U.S. Patents fall entirely within the scope of the instant claims. Specifically the methods of preparing a condensation aerosol of particles of the said U.S. Patents have specific drugs, which meet the requirement of the generic DRUG of the instant claims and the generic MMAD of the said U.S. Patents meets the limitation of the instant claims. In other words "drug" is generic to all drugs and "MMAD of less than 3 microns encompasses MMAD of less than 0.1 micron. The remaining limitations are either anticipated or obvious over the reference claims.

Due to the large number of co-pending patents, it would be a burden to the Office to have the rejections addressed individually. Thus they are grouped together.

Claim1-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application Nos. 10/815527, 10/816492, 10/768220, 10/766574, 10/813721, 10/767115, 10/816567, 10/766279, 10/766641, 10/814998, 10/718982, 10/769157, 10/769197, 10/769051, 10/768205, 10/766647, 10/792013, 10/792012, 10/766634, 10766566, 10/768293, 10/791915 and 10775586. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are anticipated by the reference claims. Claims of the instant application are generic to all that is recited in claims of the said copending Applications. That is, claims of the said copending Applications fall entirely within the scope of the instant claims. Specifically the methods of preparing a condensation aerosol of particles of the said copending Applications have specific drugs, which meet the requirement of the generic DRUG of the instant claims and the MMAD of the said copending Applications meets the particle diameter limitation of the instant claims. In other words "drug" is generic to all drugs and "MMAD of less than 3 microns" encompasses MMAD of less than 0.1 micron. The remaining limitations are either anticipated or obvious over the reference claims.

Due to the large number of co-pending applications, it would be a burden to the Office to have the rejections addressed individually. Thus they are grouped together.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.


Response to Arguments

Applicant's arguments with respect to claims 1-17 have been considered but are moot in view of the new ground(s) of rejection.

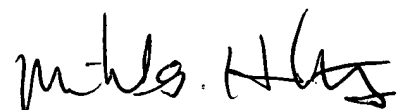
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mina Haghighatian
January 19, 2005



MICHAEL G. HARTLEY
PRIMARY EXAMINER